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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/989,797	11/20/2001	Joseph S. Adorante	2732	1582

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EXAMINER

MURPHY, JOSEPH F

ART UNIT PAPER NUMBER

1646

DATE MAILED: 03/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/989,797	Applicant(s) ADORANTE ET AL.	
	Examiner Joseph F. Murphy	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/21/2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

be

DETAILED ACTION

Formal Matters

Claims 6-10 are pending and under consideration.

Response to Amendment

The rejections of claims 1-5 have been rendered moot by cancellation of the claims, and are thus withdrawn.

New issues are set forth below.

Claim Rejections - 35 USC § 112 second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 is vague and indefinite for the recitation of several phrases. First, the claim recites that “the Na⁺ channels containing a portion where current is persistent”, this phrase is confusing, presumably it means that a certain portion of the Na⁺ channels will pass the persistent Na⁺ current. Additionally, the claim recites “the cell gaining Na⁺ via persistent Na⁺ channels open at near membrane potential”. This phrase is indefinite because it is not clear near what membrane potential the Na⁺ channels will open, i.e. the resting membrane potential, a slightly depolarized membrane potential, or near the Na⁺ equilibrium potential. Furthermore, the claim is indefinite in the recitation of the phrase “adding a Na⁺ channel blockers [sic] where the added ...” it is not clear whether a single blocker, or multiple blockers are to be added. In addition the

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phrase continues "blockers prevents depolarization". The persistent Na⁺ current maintains V_m in a depolarized state, and presumably the addition of agents which block the persistent Na⁺ current exclusively would induce repolarization of V_m as the V_m would return to the resting V_m in the absence of the gNa persistent. However, an exclusive blocker of the gNa persistent would not prevent depolarization by gNa transient.

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: there needs to be a comparison step wherein the shape of the action potential in the presence of the blocker is compared to the action potential in the absence of said blocker, wherein in the presence of a gNa persistent exclusive blocker the action potential lacks the maintenance of V_m at a depolarized potential due to the action of gNa persistent.

The term "similar" in claim 10 is a relative term that renders the claim indefinite. The term "similar" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the invention. Claims 8-9 are rejected insofar as they depend on the indefinite limitations in claims 6-7.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 6, 9-10 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,686,193 (Maher et al.). The '193 patent has a priority date of July 10, 2000.

The claims are drawn to methods of identifying Na⁺ channel blockers that preferentially block persistent but not transient Na⁺ channels, by providing a cell engineered with Na⁺ and K⁺ channels, and a Na⁺-K⁺ ATPase, adding ouabain, adding the test agent and determining if the agent blocks persistent Na⁺ channel. The claims are further drawn to methods wherein it is determined whether the agent blocks transient Na⁺ current, and measuring T_m with a dye, adding the putative blocker, and stimulating an action potential with a current, and measuring the change in T_m optically, and wherein the compounds block persistent Na⁺ channels. Claim 6, 9-10 are anticipated because the '193 patent discloses The '193 patent discloses methods of

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screening for blockers of voltage dependent Na⁺ channels, see column 54, lines 59-60, and also discloses that the method is advantageous for drug discovery where it provides the opportunity to screen for compounds that interact preferentially with one state, (i.e. use-dependent blockers). Specifically, use-dependent blockers of voltage-dependent sodium channels (column 55, lines 30-35). The '193 patent further discloses methods and systems of compound screening wherein the method comprises expressing the target ion channel in a population of host cells and placing a plurality of the host cells into each of a plurality of sample wells. A candidate drug compound is added to at least one of the plurality of sample wells; and the transmembrane potential of the cells is modulated with a repetitive application of electric fields so as to set the transmembrane potential to a level corresponding to a pre-selected voltage dependent state of the target ion channel. The reference anticipates the claims because the claims do not contain steps wherein there is a differentiation between test agent block of the persistent versus transient current, whereas in dependent claims 7 and 8, there is a further step wherein the effect of the agent on transient current is determined.

Conclusion

No claim is allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Murphy whose telephone number is (571) 272-0877. The examiner can normally be reached Monday through Friday from 7:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tony Caputa, can be reached on (571) 272-0829.

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The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Joseph F. Murphy, Ph. D.
Patent Examiner
Art Unit 1646
March 10, 2005



JOSEPH MURPHY
PATENT EXAMINER